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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,486	11/16/2000	Christopher Joseph Schofield	P02005US0	3471

7590 12/17/2002
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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,486

Applicant(s)

Schofield et al

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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Part III DETAILED ACTION

Claims 1-26 are currently pending.

Note that claims 4-11,19,20 are in "use" format and are addressed for the purposes of restriction requirement as methods of use.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claim 1 drawn to deacetoxycephalosporin C synthetase (DAOCS).
- II. Claims 2,3, drawn to complex of DAOCS with metal and substrate.
- III. Claims 4-11, drawn to use of 3-D structure of DAOCS for modification of DAOCS.
- IV. Claims 12,14, drawn to an enzyme with modified side chain binding site.
- V. Claims 13,14, drawn to an enzyme with modified penicillin binding site.

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Claims 15,16,26 will be addressed as linking claims for Groups III,IV.

V. Claim 17 , drawn to gene.

VI. Claim 18, drawn to microorganism.

VII. Claims 19,20, drawn to method of use of microorganism.

VIII. Claims 21-25, drawn to method of use of 3-D structure of DAOCS to predict structures of other enzymes.

The inventions listed as Groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is the technical feature that links Groups I-VIII. Group I is not the contribution over the prior art because it is suggested by references teaching DAOCS (see, e.g., references cited in International Search report). Further, product of Group II includes components not required for product of Group I, and products of Groups IV,V have different structures. Products of Groups IV,V differ in their structure as different moieties are being modified.

Product of Group VI is separate and distinct from Groups IV, V because the inventions are directed to different chemical types regarding the critical limitations therein; a

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completely separate chemical types of the inventions support the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately.

Microorganism of Group VI, which is merely "capable" of expressing gene of Group V, is patentably distinct as it is capable of expressing plurality of other unrelated genes. Method of use of Group VII is separate from the product Group VI, as the microorganism is capable of producing plurality of other unrelated proteins.

Each of the methods of use Groups III, VII, VIII claim a distinct and separate method which do not share a special technical feature because each method contains specific and unique method steps which are not shared by each of the other methods and each method has a unique and distinct outcome.

Because these inventions are distinct for the reasons given and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Upon election of any single one of the Groups from above the following election of species is hereby required:

Species Requirement

The claims of the Groups are individually or dependently directed to a plurality of disclosed patentably distinct species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The following election of species is required upon election of a single Groups from above claims:

A. For Group III: select:

1) select enzymes, such as DAOCS or other 2-oxoglutarate dependent enzymes (as in claim 4). Further, for other 2-oxoglutarate dependent enzymes select one of species listed in claim 5;

2) select a substrate among species listed in claims 8-10.

B. For Groups IV-VI select:

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- 1) substituted/deleted residues (as recited in claim 12 or 13), and
- 2) one of enzymes listed in claim 14;

C. For group VIII select:

- 1) type of modification: as in claim 12, in claim 13, or per specified list of residues.
- 2) In the latter case, select a residue being modified from those listed in claim 21.
- 3) enzyme from those recited in claims 22-25

Applicant is required, in response to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non - responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependant form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 13, 2002

mlb

MICHAEL BORIN, PH.D.
PRIMARY EXAMINER

